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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TRUONG, LINH T

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 05/10/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,403

Applicant(s)

HUNT ET AL.

Examiner

Linh Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Specification

Claim 14 is objected to because of the following informalities: in line 6, the phrase should read " a pressure regulator connected to the tube...." Appropriate correction is suggested.

Claim Rejections -35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being anticipated by Lina et al. (Lina) 'EPO 0 853 950 and in view of Applicant's own admission.

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For claims 8 and 9, Lina teaches a wound drainage apparatus comprising an open-celled pad 36, suction tubes 37,38 connecting the pad 36 to a collection canister 19, a tube 62 connecting the canister 19 to a vacuum pump **instead of** connecting the canister to a wall suction point or a vacuum bottle (col. 2, lines 43-51) and a fill sensor 64 for sensing when the container is filled and shutting off the vacuum (col. 12, lines 13-19). Waste canisters are well known in the art, and as admitted by Applicant in the specification (p.5, lines 3-10), to be hooked up to "standard hospital wall suction source" or "...an existing suction source..." (vacuum bottles are well known "...existing suction sources..."). (Note: the examiner takes the position that since Applicant uses a portable suction canister as admitted prior art in this instance, Lina's portable suction canister can then also be used as prior art.) Therefore it is obvious to one with ordinary skill in the art at the time the invention was made to provide the invention of Lina with a wall suction source or a vacuum bottle for a limitless or inexpensive, respectively, suction source.

For claim 10, Lina teaches a transducer 75 to measure the pressure at the wound site (col.11, lines 15-41).

For claim 11, teaches a keypad that have various vacuum pressures that a user can choose (col. 9, lines 35-46) over the pressure that is presently displayed/present between the canister and the vacuum source.

Claims 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunt et al. 'WO 9718007 (IDS) and in view of Applicant's own admission.

For claims 8-9, Hunt et al. disclose a wound drainage apparatus comprising an open-celled pad 102 (pg. 9, lines 8-9), suction tube 101 connecting pad 102 to a collection canister 100, a tube 103 connecting the canister 100 to a vacuum pump 6 and **instead of** connecting the canister to a wall suction point or a vacuum bottle (col. 2, lines 43-51), and a transducer 105 that detects pressure change when the hydrophobic filter is blocked and, thus, detects when the canister is filled and can also automatically shut off the working of the vacuum pump (pg. 6, lines 6-11). Waste canisters are well known in the art, and as admitted by Applicant in the specification (p.5, lines 3-10), to be hooked up to "standard hospital wall suction source" or "...an existing suction source..." (vacuum bottles are well known "...existing suction sources..."). (Note: the examiner takes the position that since Applicant uses a portable suction canister as admitted prior art in this instance, Lina's portable suction canister can then also be used as prior art.) Therefore it is obvious to one with ordinary skill in the art at the time the invention was made to provide the invention of Lina with a wall suction source or a vacuum bottle for a limitless or inexpensive, respectively, suction source.

For claim 10, Hunt et al. teaches a second tube 106 connected to the wound site 102 at one end and also to a pressure relief valve 8 for regulating pressure between the canister 100 and the suction source (pg. and to a second transducer 108 which

measures the pressure at the wound site (pg. 5, lines 22-26)

Claims 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunt et al. 'WO 9718007 (IDS) and in view of Peterson et al. '5,354,268.

For claims 14 and 15, Hunt et al. disclose a wound drainage apparatus comprising an open-celled pad 102 (pg. 9, lines 8-9), suction tube 101 connecting pad 102 to a collection canister 100, and a tube 103 connecting the canister 100 to a vacuum pump 6 and fully capable of connecting the canister to a wall suction point or a vacuum bottle (col. 2, lines 43-51), and a relief valve 8 controlled by a program for relieving pressure at the wound site (fig. 1 and pg. 6, lines 12-22). Hunt et al., however, do not teach a pressure regulator in electronic communication with a processor for regulating pressure from the vacuum source. Pressure regulators are well known in the aspiration art for controlling pressure flow. Peterson et al. teach an aspiration apparatus with an electronically controlled pressure regulator (col. 1, line 54-col.2, line 16 and col. 5, lines 21-22). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the wound drainage apparatus of Lina with the electronically controlled pressure regulator or Peterson in order to accurately control the pressure flow from the vacuum source.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. (Lina) 'EPO 0 853 950 in view of Applicant's own admission and further in view of Cover et al. '5,899,884.

For claim 11, in addition to the relevant 103 rejection above, Lina does not teach a flow regulator. Flow regulators are commonly used in the art to control the flow of pressure between the suction source and the canister. Cover et al. teach a flow regulator that is meant for connecting to a vacuum source and to a device that needs pressure control (col. 2, lines 35-42) for removing bodily fluids. Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the wound drainage apparatus of Lina with the flow regulator of Cover et al. for regulating pressure between the canister and the suction source.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al. 'WO 9718007 in view of Applicant's own admission and in further view of Cover et al. '5,899,884.

For claim 11, in addition to the relevant 103 rejection above, Hunt et al. do not teach a flow regulator. Flow regulators are commonly used in the art to control the flow of pressure between the suction source and the canister. Cover et al. teach a flow regulator that is meant for connection to a vacuum source and to a device that needs pressure control (col. 2, lines 35-42) for removing bodily fluids. Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the

wound drainage apparatus of Hunt et al. with the flow regulator of Cover et al. for regulating pressure between the canister and the suction source.

Claims 1, 3-7, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. (Lina) 'EPO 0853950 in view of Applicant's own admission, in view of Nichols '4,256,109 and in further view of Hunt et al. 'WO 9718807.

For claim 1, Lina teaches a wound drainage apparatus comprising an open-celled pad 36, suction tubes 37,38 connecting the pad 36 to a collection canister 19, a tube 62 connecting the canister 19 to a vacuum pump **instead of** connecting the canister to a wall suction point or a vacuum bottle (col. 2, lines 43-51) but does not teach a shut-off valve or a pressure detecting means. Waste canisters are well-known, and as admitted by Applicant in the specification (p.5, lines 3-10), to be hooked to a "standard hospital wall suction source" or "...an existing suction source..." (i.e. vacuum bottle). Shut-off valves are commonly used in wound drainage to prevent overflowing and Nichols teach a shut off valve for a medical suction canister (col. 4, lines 50-62). Hunt et al. teach a wound drainage apparatus with a transducer 105 that detects the pressure in suction tube 103 (pg. 5, lines 19-21). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the wound drainage canister of Lina with: 1) a wall suction source or a vacuum bottle for a limitless and/or inexpensive supply of suction, 2) the shut off valve of Nichols for closing the canister when it is full to prevent backflow into the suction tube and flow of liquid into the vacuum pump and 3) the transducer of Hunt et al. in order to detect sub-optimal

pressure levels in the suction tube for safe and efficient wound fluid suction.

For claims 3 and 13, in addition to the rejection above, Lina and Nichols together do not teach a pressure relief valve in communication with a processor. Pressure relief valves are well known in the art to relieve pressure. Hunt et al. teaches a pressure relief valve 8 between the canister 100 and the vacuum source 6 connected to a processor for relieving pressure and providing intermittent negative pressure at/to the wound site (fig. 1 and pg. 6, lines 12-22) instead of between the pad 102 and the canister 100. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the relief valve between the pad 102 and canister 100, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japiske*, 86 USPQ 70. Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the wound drainage canister of Lina with the pressure relief valve of Hunt et al. in order to bring the pressure at the wound site back to atmospheric pressure rapidly when needed.

For claims 4 and 12, in addition to the two rejections above, Lina and Nichols together do not teach two transducers. It is common in the aspiration art to measure/monitor the pressure in the suction tube and the suction at the wound site for safe and effective wound drainage/treatment. Hunt et al. teaches two transducers (105 and 108); transducer 105 (which is connected by a branch tube to the suction tube) measures the pressure level in suction tube 103 (fig. 1 and pg. 6, lines 6-8) and transducer 108 detects the suction level at the wound site (pg. 5, lines 24-26). Therefore, it is obvious to one with ordinary skill in the art to provide the wound drainage

apparatus of the combined inventions with two transducers for monitoring the suction levels in both the suction tube and at the wound site for safe and effective wound treatment.

For claims 5-7, Lina teaches a fill sensor 64 on the exterior of chamber 18 adjacent to canister 19 that reads a sensing profile 64A (a.k.a as an electrical capacitance device) to determine if the canister is filled or not (col. 7, lines 46- col. 8, line 5). This is also inherently a means to measure the flow rate at which the canister is filled.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. (Lina) 'EPO 0 853 950 in view of Applicant's own admission, in view of Nichols '4,256,109, in view of Hunt et al. 'WO 9718807 and in further view of Dixon et al. '5,944,703.

For claim 2, in addition to the 103 (a) rejection of claim 1 above, the combined inventions of Lina, Nichols, and Hunt et al. do not teach a flow limiting valve between the canister and suction source. It is well known in the aspiration art to have a flow limiting valve for regulating the flow of vacuum. For instance, Dixon et al. teaches a wound drainage canister 10 with an outlet port 25 connected to a vacuum source and a check valve 26 for limiting the flow of suction into the canister. Therefore, it is obvious to one with ordinary skill in the art to provide the wound drainage apparatus of the

combined inventions with a check valve in the outlet 44 (this connects to tube 62 that connects to the vacuum source) to limit the flow of air into the canister for more flow conditions/ options.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 703-605-4974. The examiner can normally be reached on Mondays to Fridays from 8:30am-5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on 703-305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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